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Empi.

Cost Effective Health Care Solutions

SUMMARY OF SAFETY AND EFFECTIVENESS
Empi, Inc. Innova® ComfortPulse® Vaginal Electrode and
Innova® ComfortPulse® Small Vaginal Electrode

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A. General Provisions

Submitter's Name:

Empi, Inc.

Submitter's Address:

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Contact Person:

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Regulatory Affairs Manager

Classification Name:

Non-implanted Electrical Continence Electrodes
(Stimulation Electrodes) 21 CFR Part 876.5320 and
Perineometers (EMG Sensing Electrodes) 21 CFR
Part 884.1425

Common or Usual Name:

Vaginal EMG Sensing and Stimulating Electrodes

Proprietary Name:

Innova® ComfortPulse® Vaginal Electrode and
Innova® ComfortPulse® Small Vaginal Electrode

B. Name of Predicate Devices

- | | |
|---|---------|
| ♦ Empi, Inc. Innova® Vaginal Stimulation Electrode | K910081 |
| ♦ Empi, Inc. Innova® Vaginal EMG Sensing Electrode | K940091 |
| ♦ Empi, Inc. Innova® Rectal or Small Vaginal
EMG Sensing Electrode | K952688 |
| ♦ Empi, Inc. Innova® Rectal Stimulation Electrode | K954272 |

C. Device Description

The Innova® ComfortPulse® Vaginal Electrodes, small and standard sizes, have three conductive elements separated by non-conductive elements of thermoplastic material. The small size electrode has a flared cylindrical shape and the standard size electrode has an hourglass shape. The electrodes are designed for repeated intermittent use in the home or clinic for up to one year by a single user. Because it is designed for use by a single user, it does not require sterilization. It does, however, require washing with soap and water and drying between uses. Both small and standard size electrodes have a permanently attached, insulated 40 inch leadwire cable that connects directly to the Stimulation System, but requires an adapter to connect to the EMG System.

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The small size electrode is approximately 2.3 inches in length from tip to end, with a maximum diameter of 0.8 inches. The standard size electrode is approximately 2.8 inches in length from tip to end, with a maximum diameter of 1.025 inches.

D. Intended Use

The Innova® ComfortPulse® Vaginal Electrodes are a component of the Innova Pelvic Floor Stimulation (PFS) System which is indicated for use in the treatment of urinary incontinence. These electrodes are also a component of the Innova® Clinical EMG System which is indicated for monitoring and evaluating EMG activity of the pelvic floor muscles.

E. Summary of Technological Characteristics

The Innova® ComfortPulse® Vaginal Electrodes use common biocompatible materials which are identical to those of the Empi, Inc. Innova® Rectal or Small Vaginal EMG Sensing Electrode. The electrodes are configured similar to currently marketed Innova® Vaginal and Rectal Electrodes used for the treatment of urinary incontinence. The design allows the electrodes to be used with the currently marketed Innova® Pelvic Floor Stimulation System and Empi's Clinical EMG Sensing Systems.

F. Non-Clinical and Clinical Test Summary

The electrodes have been verified as meeting specifications for internal wire location and integrity, initial impedance, surface inspection, material integrity (mechanical shock) and dimensions. Test results from Innova® Rectal Electrode for material stability and biocompatibility were applied to this device and not repeated because they are comprised of identical material. The results of functional testing were analyzed against product specifications and currently marketed devices. The test results demonstrate that the product meets requirements, is acceptable for its intended use and is equivalent to currently marketed devices.

An acute clinical test was performed to verify that the Innova® ComfortPulse® Vaginal Electrodes produce a pelvic floor muscle contraction equivalent to that produced by the current Innova® Vaginal Electrode as demonstrated by the generation of increased urethral pressure. In addition, both Innova® ComfortPulse® Vaginal Electrodes were assessed for their ability to sense voluntary pelvic muscle contraction by an EMG System.

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The electrically stimulated pelvic muscle contractions induced by both new Innova® ComfortPulse® Vaginal Electrodes and the currently marketed Innova® Vaginal Electrodes were clinically observable, palpable and measurable. When stimulation induced pelvic muscle contractions were compared, the new Innova® ComfortPulse® Vaginal Electrodes, both small and standard sizes, produced contractions substantially equivalent to those of the currently marketed Innova® Vaginal Electrodes. All of the electrodes discriminated between volitional contraction and rest, demonstrating that the Innova® ComfortPulse® Vaginal Electrodes, both small and standard sizes, are substantially equivalent to the currently marketed Innova® Vaginal Electrodes in sensing volitional contraction and rest.